



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/574,946 05/19/00 SHEWMAKER C CGNE.099.00U

ALISSA M. EAGLE
CALGENE LLC.
1920 FIFTH STREET
DAVIS CA 95616

HM22/0927

| EXAMINER |
|----------|
|----------|

FOX, D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/574,946

Applicant(s)

Shawmeter et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/15/01.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-130 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-130 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1638

The application should be reviewed for errors. Errors appear, for example, in claim 66, third line from the bottom, where a comma should be inserted after the first recitation of "region"; in claim 76, fourth line from the bottom, where --and-- should be inserted before "a"; and in claim 92, fifth line from the bottom, where --and-- should be inserted after "products,".

The Assignee's offer of 21 December 2000 to surrender the original patent is acknowledged.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

Application Serial No. 07/826,696 is incorrectly listed as application Serial No. 06/826,696. Furthermore, the parent applications of application Serial No. 07/998,158, namely application Serial Nos. 07/554,195 and 07/382,518, are not listed.

Claims 1-130 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

Art Unit: 1638

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Specifically, newly added application Serial Nos. 07/078,924, 07/437,764, 07/826,696 and 07/998,158, and the parent applications of '158 listed above, are not listed in the first paragraph of the first page of the specification. In addition, neither the relationships between these applications and parent application Serial No. 08/105,852, i.e. whether 08/105,852 is a continuation-in-part of any or all of them; nor the relationship between these applications with each other, i.e. whether each application is a continuation, continuation-in-part, or divisional of each other, are indicated.

Claims 19-44 and 62-130 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the

Art Unit: 1638

meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Claims 19-29 and 62-130 are drawn to DNA constructs comprising seed-preferred or seed-specific promoters, plants transformed therewith, and methods for selectively expressing genes of interest in seed tissue. Claims 19-44 and 62-130 are drawn to DNA constructs comprising light-regulatable or chloroplast-containing-tissue-preferred promoters, plants transformed therewith, and methods for selectively expressing genes of interest in chloroplast-containing tissue such as leaves. Claims 65-80 are drawn to DNA constructs comprising promoters which are preferentially expressed at a particular developmental stage of plant growth, which encompasses seed or embryo development or leaf development. However, claims drawn to this subject matter were cancelled during the prosecution of parent application Serial No. 08/105,852, in response to rejections applied against these claims under 35 USC 112, 102 and 103, as set forth below.

Original claims 11-14 and 37-41 of parent application '852 were drawn to seed-specific promoters and their use, as were claims 42-49 and 51-66 added by the preliminary amendment of 7 March 1994 (Paper No. 5). In the Office action of 20 June 1994, Paper No. 7, on pages 6-7, these claims were rejected under 35 USC 112, first paragraph, as not being enabled for a scope broader than that which limited claims to the exemplified three particular seed-specific promoters from the plant genus *Brassica*. These claims were also rejected under 35 USC 103 on pages 16-17 of that Office action.

Art Unit: 1638

The amendment of 27 December 1994 (Paper No. 10) cancelled claim 45, and the amendment of 12 April 1995 (Paper No. 12) added claims 70-81, 85-88 and 94-95 drawn to seed-specific promoters. The Office action of 21 June 1995 (Paper No. 14) maintained the rejection under 35 USC 112 stated above, and applied it to the new claims (see pages 3-6 of that action). That Office action also withdrew the outstanding art rejection over those claims (page 10 of that action). The personal interview of 26 September 1995 (Paper No. 15) indicated that claims limited to the exemplified seed-specific promoters would be deemed free of the prior art and free of rejection under 35 USC 112.

The amendment of 23 October 1995 (Paper No. 16) cancelled claims 11-14, 37-40, 48-49, 53, 64-66, 71-73, 76-78, 80, 85-88 and 94-95, drawn to seed-specific promoters, and added claims 102 and 107-110 also drawn to seed-specific promoters. The amendment also amended product claims such as claim 1 to limit them to the exemplified seed-specific promoters. The Office action of 29 August 1996 (Paper No. 22) withdrew the rejection of the claims under 35 USC 112, first paragraph, but added a new rejection under 35 USC 103 over a newly discovered patent (see pages 4-5 of that action).

The amendment of 2 January 1997 (Paper No. 26) cancelled claims 1-3, 6, 10, 26-28, 32, 36, 41, 44, 50-52, 54-57, 60, 63, 67, 69, 75, 79, 81, 98-100, and 107-112, encompassing seed-specific promoters and methods for their use. In addition, claims 22, 42, 58, 62 and 70 were amended to delete any reference to seed-specific promoters. As a result, all of the claims remaining in the application were drawn to fruit-specific promoters and methods for their use.

Art Unit: 1638

These remaining claims were allowed on 1 April 1997 (Paper No. 28), and correspond to claims 1-18 of U.S. Patent 5,753,475.

Furthermore, original claims 5-6, 26, 31-32 and 41 of the '852 parent application were drawn to chloroplast-containing-tissue-specific or light-inducible promoters, and methods for their use to express genes selectively in chloroplast-containing tissue such as leaves, upon exposure to light. New claims 49-57, added by the preliminary amendment of 7 March 1994 (Paper No. 5), were also drawn to this subject matter. The Office action of 20 June 1994 (Paper No. 7) rejected these claims under 35 USC 112, first paragraph, as being not enabled for a scope broader than that limited to the exemplified RUBISCO (ribulose biphosphate carboxylase small subunit gene, also known as SSU) promoter (see pages 7-8 of that action). Product claims drawn to DNA constructs comprising an SSU promoter, and plant cells transformed therewith, were also rejected under 35 USC 102(e) over Rogers et al (see pages 11-12 of that action).

The amendment of 27 December 1994 (Paper No. 10) added claim 69 drawn to an SSU promoter. The Office action of 21 June 1995 (Paper No. 14) maintained the rejection under 35 USC 112 stated above (see pages 6-7 of that action), and also maintained the rejection under 35 USC 102(e) stated above (see page 8 of that action). The personal interview of 26 September 1995 (Paper No. 15) indicated that method claims limited to the exemplified chloroplast-containing-tissue-specific promoter would be allowable, while product claims reciting that promoter would remain rejected under 35 USC 102(e).

Art Unit: 1638

The amendment of 23 October 1995 (Paper No. 16) cancelled claims 5, 49 and 53, and added claim 111, drawn to a method of using an SSU promoter. The Office action of 29 August 1996 (Paper No. 22) withdrew the rejection under 35 USC 112 and 35 USC 102(e), as the remaining claims were limited to the exemplified SSU promoter, or were limited to methods of using the promoter to effect light-inducible gene expression, wherein such methods were not taught by Rogers et al. The claims were subjected to statutory and obviousness-type double patenting rejections (see pages 2-3 of that action).

The amendment of 2 January 1997 (Paper No. 26) cancelled claims 1-3, 6, 10, 26-28, 32, 36, 41, 44, 50-52, 54-57, 60, 63, 67, 69, 75, 79, 81, 98-100, and 107-112, encompassing chloroplast-containing-tissue-specific promoters and methods for their use. In addition, claims 22 and 70 were amended to delete any reference to chloroplast-containing tissue-specific promoters. As a result, all of the claims remaining in the application were drawn to fruit-specific promoters and methods for their use. These remaining claims were allowed on 1 April 1997 (Paper No. 28), and correspond to claims 1-18 of U.S. Patent 5,753,475.

Accordingly, claims 19-44 and 62-130 are an improper attempt to recapture subject matter which was surrendered in the application for the patent upon which the present reissue is based.

The effective filing date for claims 19-29 and 62-130, insofar as they are drawn to seed-specific promoters and their use, is 31 July 1986, the filing date of parent application Serial No. 06/891,529 which was the earliest parent to teach such a promoter. The effective filing date for claims 19-44 and 62-130, insofar as they are drawn to chloroplast-containing-tissue-specific

Art Unit: 1638

promoters and their use, is 17 November 1985, the filing date of parent application Serial No. 06/692,605 which was the earliest parent to teach such a promoter. The effective filing date for claims 1-29 and 45-130, insofar as they are drawn to fruit-specific promoters and their use, is 26 May 1987, the filing date of parent application Serial No. 07/054,369 which was the earliest parent to teach such a promoter.

Claims 19-29 and 62-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,420,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a seed-specific promoter and plant cells containing them as claimed in the patent to obtain the DNA constructs containing a seed-specific promoter and methods for their use to obtain transformed plant cells and plants containing them as claimed in the instant application.

Claims 19-44 and 62-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,750,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain plant cells containing them as claimed in the patent to obtain the DNA constructs

Art Unit: 1638

containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain transformed plant cells and plants containing them as claimed in the instant application.

Claims 1-29 and 45-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,943,674.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them as claimed in the patent to obtain the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them as claimed in the instant application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1638

Claims 34-35, 76, 101-108 and 113-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 113-114, 117, 121 and 124, and dependent claims 35, 115-116, 118-120, 122-123 and 125-128, are indefinite for failing to employ proper Markush terminology per MPEP 2173.05(h), in their recitation of “and” twice. The following amendment would overcome this rejection: Replace the “and” before “fungi” with --or--.

Claims 76, 108 and 124, penultimate line, are indefinite in their recitation of “said... translational initiation region specifically regulated” which lacks antecedent basis in the claims. Only the transcriptional initiation region, and not the translational initiation region, is characterized as tissue-specific earlier in the claims.

Claims 101, 105 and 108, and dependent claims 102-104 and 106-107, are indefinite in their recitation of “which is from a gene native to a plant host or a mutant of a gene which is native to a plant host” as it is unclear to which of the preceding claim elements this phrase refers-- the DNA sequence of interest, the gene from which the promoter was derived, or something else.

Claims 129-130 are indefinite in their recitation of “other than the native coding sequence of said gene that is not phaseolin” as it is unclear whether the DNA sequence of interest or the promoter region is not supposed to be from the phaseolin gene. Furthermore, the claims are indefinite for referring to a protein, namely phaseolin, as a gene.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-29 and 62-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the use of *Brassica*-derived seed-specific promoters for seed-specific gene expression, transcription, or phenotypic alteration; or for light-inducible/chloroplast-containing-tissue-specific or fruit-specific promoters and methods for their use; does not reasonably provide enablement for claims broadly drawn to the use of any promoter or any regulatory sequence from any plant source to effect seed-specific gene expression, transcription or phenotypic alteration; or any promoter which would effect any type of plant developmental stage-specific expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only demonstrates the use of light-inducible and fruit-specific promoters in mature plants or ripening fruits, respectively, or the use of three seed-specific promoters from the same plant genus for the seed-specific expression of heterologous genes in intact seeds. No guidance is presented regarding the identification, isolation, or evaluation of seed-specific promoters from any other plant genus for their ability to effect seed-specific heterologous gene expression. Furthermore, no guidance is presented regarding the identification, isolation or evaluation of regulatory sequences effecting developmental stage-specific expression in a multitude of non-exemplified plant tissues such as roots, flowers, or stems, or at a multitude of

Art Unit: 1638

non-exemplified plant developmental stages such as seed germination or immature seedling stage (as claimed in claims 65-80 and 129-130), for the developmental stage-specific expression of heterologous genes. In contrast, the claims are broadly drawn to any type of promoter or regulatory sequence from any source and of any sequence which would be sufficient to effect seed-specific gene expression, or to any promoter able to cause developmental stage-specific expression in a multitude of non-exemplified plant tissues and at a multitude of non-exemplified developmental stages such as germination or seedling growth.

The identification of tissue-specific genes, and the isolation of putative tissue-specific promoters therefrom, is unpredictable. Tissue-specific gene expression could be the result of a variety of complex factors other than a tissue-specific promoter immediately upstream of the structural gene. Such alternate factors include distant genes encoding regulatory proteins, activator/operator/repressor systems, far upstream or downstream enhancer elements, changes in the phosphorylation of transcriptional proteins, export of mRNA from DNA found in other organelles or tissues, transposable elements, and post-transcriptional controls such as alternative RNA splicing (see, e.g., *Molecular Biology of the Cell*, pages 553-569; 588-597, and 606-607).

Thus, multiple attempts to isolate the putatively tissue-specific or developmental stage-specific promoters associated with a multitude of genes encoding tissue-specific or developmental stage-specific gene products, including a multitude of non-exemplified seed-specific genes from a multitude of plant species, would prove unsuccessful.

Art Unit: 1638

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of non-exemplified promoter types or other types of regulatory sequences for their ability to effect seed-specific gene expression; or to identify, isolate and evaluate a multitude of non-exemplified developmental stage-specific promoters for their ability to effect developmental stage-specific expression in a multitude of non-exemplified tissues..

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a “mere germ of an idea does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Claims 19-29 and claims 62-130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any type of seed-specific promoter or regulatory region from any plant source and of any length or sequence (claims 19-29, 62-64, and 81-128), or to any developmental stage-specific or tissue-specific promoter from any gene or plant and of any sequence (claims 65-80 and 129-130). No guidance is presented for any seed-specific regulatory region other than the promoters from three particular structural genes isolated from the same plant genus of *Brassica*. Furthermore, no guidance is presented for any tissue-specific promoter

Art Unit: 1638

other than seed-, fruit-, or chloroplast-containing-tissue-specific promoters; and no guidance is presented for any of a multitude of non-exemplified developmental stage-specific promoters.

Given the claim breadth and lack of guidance as discussed above, one skilled in the art would not recognize Applicants to be in possession of the broadly claimed genus, given their limited disclosure of species. Accordingly, the specification fails to provide an adequate written description of the invention as broadly claimed.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 129-130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1638

The claims are drawn to methods of plant cell transformation with DNA constructs which do not comprise portions of the phaseolin gene. However, there is no basis for this limitation in the specification or the claims of parent application Serial No. 08/105,852, upon which this reissue application is based. Accordingly, these claims are drawn to NEW MATTER.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 30, 33-34, 38-41 and 43-44 are rejected under 35 U.S.C. § 102(b) as being anticipated by each of Horsch et al. and DeBlock et al.

Each of Horsch et al. and DeBlock et al. teach plants and their progeny which contain an *Agrobacterium*-introduced DNA construct comprising T-DNA and a constitutive opine synthase promoter expressible in any tissue including seeds and a heterologous gene encoding an enzyme conferring resistance to a phytotoxic antibiotic compound, wherein the production of seeds would be an inherent feature of the production of progeny, and wherein said promoters are "regulatable" in chloroplast-containing tissue such as leaves grown in light, by being capable of being activated. Note that page 11 of the parent '852 specification, lines 11-29 characterize the opine synthase promoters as being encompassed by the invention.

Art Unit: 1638

Claims 30, 33-34, 38-41 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Zambryski et al.

Zambryski et al teach plant cells and plants which contain a DNA construct comprising an opine synthase promoter and a heterologous gene conferring resistance to a phytotoxic antibiotic compound, wherein said promoters are "regulatable" as discussed above (see, e.g., paragraph bridging pages 2143 and 2144; page 2145, column 1, second full paragraph; paragraph bridging pages 2148 and 2149; page 2149, column 1).

Amendment of claims 30 and 33-34 to replace "light-regulatable" with --light-inducible-- would obviate the above two rejections.

Claims 30, 32-35 and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Rogers et al (U.S. Patent 5,034,322 filed 5 April 1989, effective filing date 17 January 1983).

Rogers et al teach plant cells comprising DNA constructs comprising opine synthase promoters or the soybean SSU promoter for the expression of a heterologous kanamycin (phytotoxic antibiotic) resistance gene or a heterologous *aroA* gene encoding a mutant EPSPS conferring resistance to the herbicide glyphosate in transformed plant cells (see, e.g., column 16, lines 47-68; column 17, lines 1-51; column 18, line 63-column 20, line 47). Rogers et al also teach the high levels of transcription resulting from said SSU promoter (see, e.g., column 16, lines 56-61). The ability of the soybean SSU promoter to be regulated (or induced) by light would have been an inherent property. Rogers et al also teach that the opine synthase promoters are not expressed in bacterial cells but are expressed in plant cells (see, e.g., column 7, lines 27-29).

Art Unit: 1638

Thus, the opine synthase promoters are “regulatable” in that they are influenced by the plant cell environment, i.e. a light-containing environment in which chloroplast-containing tissues such as leaves are grown.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-31, 33-36 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Horsch et al, DeBlock et al and Zambryski et al.

Each of Horsch et al, DeBlock et al and Zambryski et al teach plant cells and plants containing DNA constructs which contain a regulatable promoter and a heterologous gene

Art Unit: 1638

conferring resistance to a phytotoxin, as discussed above, but do not teach the use of antisense constructs or glyphosate resistance genes.

It would have been obvious to one of ordinary skill in the art to utilize the DNA constructs comprising regulatable promoters ligated to phytotoxin-resistance encoding genes as taught by each of Horsch et al, DeBlock et al and Zambryski et al, and to modify that by incorporating other known genes encoding resistance to other phytotoxins such as herbicides, or other known genes encoding antisense RNA for its known effect on phenotypic alteration, given the suggestion by each of the references of the utility of their promoters and techniques for obtaining a multitude of transformed agronomic plants exhibiting a multitude of traits, and given the recognition by those of ordinary skill in the art that choice of known DNA of interest and choice of transformable plant species would have been the optimization of process parameters.

Amendment of claims 30 and 33-34 to replace "light-regulatable" with --light-inducible-- would obviate this rejection.

Claims 30-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zambryski et al taken with Rogers et al (U.S. Patent 5,034,322).

Zambryski et al teach a method for plant cell transformation with a DNA of interest under the control of a plant-expressible promoter, as discussed above. Zambryski et al also suggest the utility of their process for the introduction of a variety of genes of interest into plants (see, e.g., page 2144, column 1, top paragraph; page 2149, column 1, first full paragraph, last sentence; page 2149, column 1, third full paragraph, first two sentences).

Art Unit: 1638

Zambryski et al do not teach plant transformation with an SSU promoter or a gene encoding glyphosate resistance or antisense RNA.

Rogers et al teach DNA constructs comprising the SSU promoter ligated to a heterologous glyphosate resistance gene for plant cell transformation, and also teach the strength of the SSU promoter, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method and DNA constructs for plant transformation taught by Zambryski et al, and to modify those by incorporating the SSU promoter and glyphosate resistance gene taught by Rogers et al, given the recognition by those of ordinary skill in the art of the advantages of obtaining high levels of heterologous gene product, the suggestion by Zambryski et al to utilize a variety of DNA constructs, and the recognition by those of ordinary skill in the art that choice of known DNA of interest, including antisense-encoding DNA for phenotypic alteration, and choice of transformable plant species, would have been the optimization of process parameters.

Claims 19-27 and 62-130 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al.

Hall et al. teach the Agrobacterium-mediated transformation of sunflower, alfalfa and tobacco cells with a heterologous phaseolin promoter and phaseolin structural gene, wherein expression of the phaseolin gene is highly regulated and seed-specific in the native bean, wherein intronless phaseolin genes were also constructed, wherein deletions of the tumor genes on the Ti plasmid were performed, and wherein whole tobacco plants were recovered which expressed high

Art Unit: 1638

levels of the protein in the seed in the same pattern in which it was expressed in the native bean (see, e.g., column 9, lines 55-68; column 10, lines 1-16 and 57-59; column 19, lines 30-67; columns 20-21; column 22, lines 1-41; column 24, lines 9-61; columns 28-31, especially column 29, lines 1-5 and 60-68). Hall et al also teach phaseolin cDNA from which the transcription initiation region of the native gene, and the upstream promoter, could have been deduced if desired (see, e.g., column 19, lines 57-67; column 20, lines 1-7). Hall et al. also teach the transformation of alfalfa cells with a chimeric gene comprising the nopaline synthase promoter and a gene encoding the neomycin phosphotransferase enzyme, and suggest the transformation of a variety of plants with a plant gene-derived promoter such as the phaseolin promoter and a variety of structural genes such as genes conferring disease resistance, herbicide resistance, or flavor components (see, e.g., column 24, lines 9-61; column 10, lines 45-59; and claims 11-30).

Hall et al. do not explicitly teach a chimeric gene construct comprising the phaseolin promoter and a heterologous structural gene.

Sengupta-Gopalan et al. teach that a heterologous gene comprising the phaseolin promoter and phaseolin structural gene is expressed in a highly seed-specific manner in the heterologous species tobacco following Agrobacterium-mediated transformation, and that the phaseolin promoter contains all of the necessary components for seed-specific expression; and suggest the value of tissue-specific heterologous gene expression in transformed plants (see, e.g., page 3320, Abstract; page 3321, Table 1 and column 1; page 3323, column 2, third full paragraph; page 3324, column 2, top paragraph).

Art Unit: 1638

It would have been obvious to one of ordinary skill in the art to utilize the phaseolin promoter which functions in a variety of heterologous plant species as taught by Hall *et al.* for the seed-specific expression of a variety of heterologous genes such as the neomycin phosphotransferase gene taught by Hall *et al.* in a variety of heterologous plants, as suggested by Hall *et al.* and Sengupta-Gopalan *et al.* Choice of transformable and regenerable heterologous plant species or heterologous structural gene would have been the optimization of process parameters. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 28-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall *et al.* (U.S. Patent 5,504,200) taken with Sengupta-Gopalan *et al.* as applied to claims 19-27 and 62-130 above, and further in view of Zambryski *et al.* taken with Pedersen *et al.*

Hall *et al.* taken with Sengupta-Gopalan *et al.* teach the transformation of a variety of plant species including alfalfa with a tumor gene-deleted Agrobacterium tumefaciens vector comprising the phaseolin promoter and heterologous structural gene for seed-specific gene expression as discussed *supra*, but do not teach soybean transformation or the obtention of whole transformed legume plants.

Zambryski *et al.* teach a method of tumor-free transformation comprising plant infection with tumor gene-free Agrobacterium strains containing genes for opine synthase and antibiotic resistance under the control of a plant-expressible promoter, and suggest the wide use of this

Art Unit: 1638

method for the introduction of heterologous genes into plants (see, e.g., paragraph bridging pages 2143 and 2144; page 2145, column 1, second full paragraph; paragraph bridging pages 2148 and 2149; page 2149, column 1).

Pedersen et al. teach the injection of soybean plants with Agrobacterium to effect transformation (see, e.g., page 201, column 2, third full paragraph; page 203, column 1, bottom paragraph, Figure 4).

It would have been obvious to one of ordinary skill in the art to utilize the method of tumor gene deletion and gall-free Agrobacterium-mediated transformation for the seed-specific expression of heterologous structural genes under the control of the phaseolin promoter in a variety of plant species including alfalfa as taught by Hall et al. taken with Sengupta-Gopalan et al., and to modify that method by incorporating the tumor deletion and whole plant regeneration taught by Zambryski et al. and the soybean-infecting Agrobacterium plasmid taught by Pedersen et al., given the recognition by those of ordinary skill in the art that each would have continued to function in its known and expected manner, and the recognition of the benefits of transforming a wide variety of plant species including soybean, as suggested by Hall et al. taken with Sengupta-Gopalan et al. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 1-18 and 45-61 are deemed free of the prior art for the reasons presented in allowed parent application 08/105,852 corresponding to U.S. Patent 5,753,475.

Art Unit: 1638

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 25, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.